

ORIGINAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

JOHN M. FLACK ET AL.

Serial No.: 10/036,202

Filed: December 27, 2001

For: COMPUTER-IMPLEMENTED METHOD AND SYSTEM  
FOR MANAGING PATIENT HEALTHCARE  
AND EVALUATING PATIENT KIDNEY FUNCTION

Attorney Docket No.: MTS 0102 PUS



Group Art Unit: 37626

Examiner: Robert D. Rines

**APPEAL BRIEF UNDER 37 C.F.R. § 41.37**

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Sir:

This is an amended Appeal Brief from the Notice of Non-Compliant Appeal Brief mailed March 28, 2007 and the final rejection of claims 1-19 of the Office Action mailed on September 12, 2006 for the above-identified patent application.

**I. REAL PARTY IN INTEREST**

The real parties in interest are the individual Applicants, John M. Flack, M.D. and Lowell A. Hedquist.

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8 (FIRST CLASS MAIL)**

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## II. RELATED APPEALS AND INTERFERENCES

None.

## III. STATUS OF CLAIMS

Claims 1-19 are pending. These claims stand rejected and are the subject of this Appeal.

## IV. STATUS OF AMENDMENTS

None.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites a computer-implemented healthcare management system. Input is received into the system defining patient information including his or her medical record. (Specification, p. 12, line 24 — p. 14 line 28.) In one embodiment, this information is input through one or more graphical user interfaces, such as those illustrated in Figures 3-4.

The system calculates the patient's estimated glomerular filtration rate based on the patient's medical record. (Specification, p. 22, lines 9-24.) The following illustration, reproduced from Figure 17, is an example of an "Estimated Glomerular Filtration Rate" (EGFR) calculator:

The screenshot shows a window titled "EGFR Calculator". At the top, it displays "Patient: Doe, John" and "SSN: 1233-12-1234" with a "Close" button to the right. Below this is a warning: "Always verify that the information below is accurate!". A large bracket on the left side of the input fields is labeled "236". The input fields are: Age: 75 (yr), Sex: Male (dropdown), Height: 69.0 (in), Weight: 172.0 (lb), and Serum Creatinine: 1.6 (mg/dl). Below these fields is a button labeled "EGFR 39.3". At the bottom, a note states: "Note: Although the data is imported from the patient record, field changes made on this form are NOT stored in the patient record."

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Fig. 17

At page 22, the Specification provides example mathematical formulas for calculating a patient's estimated glomerular filtration rate:

$$EGFR = \left[ \frac{((140 - AGE) \times WEIGHT(kg))}{72 \times SCR} \right] \times \left[ \frac{1.73}{BSA} \right]$$

$$BSA = 0.007184 \times [HEIGHT(cm)^{0.725}] \times [WEIGHT(kg)^{0.425}]$$

The system also generates a medical treatment recommendation for the patient. The medical treatment recommendation is based on the patient's medical record and the estimated glomerular filtration rate calculation described above. Example medical treatment recommendations are provided in Table 2, recorded on pages 25-28 of the Specification.

The system also provides one or more treatment goals for the patient. One example is a LDL cholesterol goal. (Specification, p. 22, line 25 — p. 23, line 14.) The following illustration, reproduced from Figure 18, is an example of a LDL cholesterol goal calculator:

LDL Cholesterol

Patient: Doe, John      Close

SSN: 1233-12-1234

Always verify that the information below is accurate!

Goal LDL: Less than or equal to 100 mg/dl

Age: 75

Sex: Male

Family Hx of CHD: No

Smoking: No

Hypertension: Yes

CHD: Yes

Diabetes: No

HDL: 60 mg/dl

LDL: 150 mg/dl

\*required field if CHD is "No"

LDL / HDL Lab Results Summary:

VDAT	FASTING	LDL	HDL
01/03/1999	Yes	150	60

Independent claim 10 recites a computer-implemented method healthcare management system. Input is received into the system defining patient information including his or her medical record. (Specification, p. 12, line 24 — p. 14 line 28.) Next, the patient's estimated glomerular filtration rate is calculated based on the patient's medical record. (Specification, p. 22, lines 9-24.) At page 22, the Specification provides example mathematical formulas for calculating a patient's estimated glomerular filtration rate.

In another step of the method, a medical treatment recommendation is generated for the patient. The medical treatment recommendation is based on the patient's medical record and the estimated glomerular filtration rate calculation described above. Example medical treatment recommendations are provided in Table 2, recorded on pages 25-28 of the Specification.

The method also includes providing one or more treatment goals for the patient. One example is a LDL cholesterol goal. (Specification, p. 22, line 25 — p. 23, line 14.)

Independent claim 19 recites a computer-implemented healthcare management system. The limitations of this claim are recited in means-plus-function format, so the following description provides example corresponding structures from the patent application. Input is received into the system defining patient information including his or her medical record. (Specification, p. 12, line 24 — p. 14 line 28.) The system may comprise a stand-alone or networked computer system such as that illustrated in Figure 1, and described in the specification at pages 10-11. In one embodiment, this information is input through one or more graphical user interfaces, such as those illustrated in Figures 3-4.

The system calculates the patient's estimated glomerular filtration rate based on the patient's medical record. (Specification, p. 22, lines 9-24.) Figure 17, reproduced above, is an example of an "Estimated Glomerular Filtration Rate" (EGFR) calculator.

At page 22, the Specification provides example mathematical formulas for calculating a patient's estimated glomerular filtration rate:

$$EGFR = \left[ \frac{((140 - AGE) \times WEIGHT(kg))}{72 \times SCR} \right] \times \left[ \frac{1.73}{BSA} \right]$$

$$BSA = 0.007184 \times [HEIGHT(cm)^{0.725}] \times [WEIGHT(kg)^{0.425}]$$

The system also generates a medical treatment recommendation for the patient. The medical treatment recommendation is based on the patient's medical record and the estimated glomerular filtration rate calculation described above. Example medical treatment recommendations are provided in Table 2, recorded on pages 25-28 of the Specification.

The system also provides one or more treatment goals for the patient. One example is a LDL cholesterol goal. (Specification, p. 22, line 25 — p. 23, line 14.) Figure 18, reproduced above, is an example of a LDL cholesterol goal calculator.

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

In the final Office Action mailed September 12, 2006, claims 1-19 were rejected under 35 U.S.C. 103(a) as being obvious in view of Pestotnik et al. (U.S. Pub. No. 2004/0260666).

## **VII. ARGUMENT**

### **A. Pestotnik Does Not Teach Or Suggest An Estimated Glomerular Filtration Rate Calculation**

Each independent claim recites (i) the calculation of a patient's estimated glomerular filtration rate based on the information input defining the patient's medical record, and (ii) the generation of a medical treatment recommendation based upon that value.

The Examiner admits that Pestotnik does not teach these limitations, and the Examiner does not find them in any other prior art reference. (Final Office Action, p. 4.) Instead, the Examiner interprets the Pestotnik reference in a fashion that, according to the Examiner, renders the claims obvious to one of ordinary skill in the art. (*Id.*) The Examiner cites paragraph 85 of the Pestotnik reference to support the obviousness rejection for these limitations:

[0085] The medical information and data stored within knowledge module 226 are based on information from experts

within the relevant fields of medicine, such as Geriatric Medicine, Genetic Medicine and Gene Therapy, Cardiovascular diseases, Respiratory diseases, and the like. Knowledge module 226, therefore, may include information related to, but not limited to, Critical Care Medicine, Renal diseases, Genitourinary diseases, Gastrointestinal diseases, Diseases of the liver, gallbladder, and bile ducts, Hematologic diseases, Oncology, Metabolic diseases, Nutritional diseases, Endocrine diseases, Women's Health, Diseases of bone and bone mineral metabolism, Diseases of the immune system, Musculoskeletal and connective tissue diseases, Infectious diseases, HIV and Acquired immunodeficiency syndrome, Diseases of protozoa and metazoa, Neurological Diseases, Eye, Ear, Nose, and Throat diseases, Skin diseases, Pediatric Medicine, and the like.

This paragraph does not teach or suggest the calculation of anything, let alone a patient's estimated glomerular filtration rate based on his or her medical record as recited in the claims.

Furthermore, Pestotnik describes a system that is unable to generate a medical treatment recommendation that is based on that calculation. Pestotnik's uses "inference engines" to apply "rules and parameters" for generating medical diagnoses and patient care recommendations. (Pestotnik, para. 90.) The "rules and parameters" of Pestotnik are a series of if-then statements. (Pestotnik, Table 6, Figures 13A-13F). With this architecture, Pestotnik is unable to *calculate* information (such as an estimated glomerular filtration rate) from patient medical record data, or generate a treatment decision based upon that calculation. Pestotnik does not teach calculations of any kind. Due to its if-then rule architecture, Pestotnik cannot be modified as the Examiner suggests to meet the limitations of the pending claims.

**B. Pestotnik Does Not Teach Or Suggest  
The Generation Of Treatment Goals**

The Examiner cites Pestotnik paragraphs 94, 150 and 151 for the calculation of one or more treatment goals for the patient, another limitation that is recited in each independent claim. But as explained above, Pestotnik does not teach *any* calculations. The paragraphs the Examiner cites make no mention of this claim limitation either:

[0094] In one setting, a clinician may request that progress note module 236 summarize the decision-supported patient data

generated by inference module 232. The summarized decision-supported patient data contains the pertinent information related to the medical condition of the patient in an easily viewed display. For example, if the patient has diabetes, progress note module 236 will generate a decision-supported progress note that summarizes the pertinent medical parameters associated with the patient's diabetes, such as the most recently acquired heart rate, blood pressure, blood sugar level, and the like, while providing warnings or alerts to the clinician. Similarly, when a therapeutic regimen is suggested, progress note module 236 summarizes decision-supported patient data includes drug name and type, dose, route, interval and duration of therapy specific to the patient and the drug, patient demographics, and the like, while providing warnings or alerts to the clinician.

[0150] Following obtaining the etiology, decision-support module 210 gathers any susceptibilities and any mitigating factors. In this particular example, no susceptibilities are necessary. In contrast, however, a number of mitigating factors may be displayed or presented to the clinician. Such mitigating factors may include, but are not limited to pregnancy or post-partum state, renal transplant or other immunosuppression, use of diaphragm prior to onset, recurrence, early relapse of initial treatment failure, diabetes, neurogenic bladder, recent urologic surgery/instrumentation, obstruction or abnormal urological anatomy, duration of symptoms for longer than seven (7) days, age less than three (3) years, and the like. Each mitigating factor may include a rule stored in knowledge module 226 that may be used to guide the decision-support process of the present invention.

[0151] Upon completing the above analysis, decision-support module 210 generates an updated decision-supported patient data and decision-supported progress note with a ranked list of recommendations, as represented by blocks 376 and 378. In this example, decision-support module 210 also identifies whether the existing medical care is successful in treating the urinary tract infection and generates a recommendation based upon the current success of the regime.

The Applicants' claims recite a valuable invention for assisting physicians in patient treatment. The Examiner has not found a teaching or suggestion in the prior art of the estimated glomerular filtration rate calculation, treatment recommendations that are based on

that calculation, or the generation of treatment goals — all of which are recited in each independent claim. Accordingly, the Examiner has failed to establish *prima facie* obviousness for independent claims 1, 10 and 19.

The Applicants respectfully request that the Examiner's pending rejection be withdrawn.



### **VIII. CONCLUSION**

For the foregoing reasons, the Appellants respectfully submits that each rejection has been fully replied to and traversed and that the case is in condition to pass to issue. The Board is respectfully requested to pass this case to issue.

The fee of \$250 as applicable under the provisions of 37 C.F.R. § 41.20(b)(2) was previously submitted with the original Appeal Brief. Please charge any additional fee or credit any overpayment in connection with this filing to our Deposit Account No. 02-3978.

Respectfully submitted,

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Enclosure - Appendices

### **VIII. CLAIMS APPENDIX**

1. A patient healthcare management system having a capability to evaluate patient kidney function, the system configured to:

receive input defining a patient's medical record including the patient's demographic information, medical condition and diagnosis;

calculate the patient's estimated glomerular filtration rate based on the patient's medical record;

output at least one medical treatment recommendation wherein the recommendation is based on the patient's medical record and estimated glomerular filtration rate; and

calculate and output at least one treatment goal for the patient.

2. The system of claim 1 wherein the at least one treatment goal for the patient comprises at least one of:

a goal blood pressure, a goal lipid level, a goal cholesterol level and a goal hemoglobin A1C level.

3. The system of claim 1 additionally configured to receive input specifying a treatment for the patient.

4. The system of claim 1 additionally configured to output an indication as to whether, based on the patient's medical record, the at least one medical treatment goal has been met.

5. The system of claim 1 wherein a plurality of clinical treatment algorithms are applied to the patient's medical record to generate the at least one treatment recommendation and the at least one patient treatment goal.

6. The system of claim 1 additionally configured to:  
receive input specifying a patient's current medication(s);  
receive input specifying a new prescription for the patient; and  
generate an alert if the prescribed medication may antagonize a medication the patient is currently taking.

7. The system of claim 1 further configured to:  
receive input defining a plurality of patient medical records comprising patient demographic information, medical condition, diagnosis and treatment;  
receive input defining at least one medical record parameter to extract from the plurality of medical records; and  
automatically generate a report containing an aggregate of the at least one medical record parameter extracted from the plurality of medical records.

8. The system of claim 7 further configured to receive input defining a subset of the plurality of patient medical records from which to extract the at least one medical record parameter.

9. The system of claim 1 additionally configured to receive input, for each patient encounter with his or her healthcare provider, defining the patient encounter wherein each defined patient encounter is appended to the patient's medical record.

10. A computer-implemented patient healthcare management method involving the evaluation of patient kidney function, the method comprising:  
defining a patient's medical record including the patient's demographic information, medical condition and diagnosis;  
calculating the patient's estimated glomerular filtration rate based on the patient's medical record;

automatically generating at least one medical treatment recommendation based on the patient's medical record and estimated glomerular filtration rate; and calculating at least one treatment goal for the patient.

11. The method of claim 10 wherein the at least one treatment goal for the patient comprises at least one of a goal blood pressure level, a goal lipid level, a goal cholesterol level and a goal hemoglobin A1C level.

12. The method of claim 10 further comprising specifying a treatment for the patient.

13. The method of claim 10 further comprising indicating whether, based on the patient's medical record, the at least one patient treatment goal has been met.

14. The method of claim 10 wherein a plurality of clinical treatment algorithms are applied to the patient's medical record to generate the at least one treatment recommendation and the at least one patient treatment goal.

15. The method of claim 10 further comprising:  
specifying the patient's current medications;  
specifying a new prescription for the patient; and  
generating an alert if the prescribed medication may antagonize a medication the patient is currently taking.

16. The method of claim 10 further comprising:  
defining a plurality of patient medical records comprising patient demographic information, medical condition, diagnosis and treatment;  
defining at least one medical record parameter to extract from the plurality of medical records; and

automatically generating a report containing an aggregate of the at least one medical record parameter extracted from the plurality of medical records.

17. The method of claim 16 further comprising defining a subset of the plurality of patient medical records from which to extract the at least one medical record parameter.

18. The method of claim 10 further comprising defining each patient encounter with his or her healthcare provider wherein the defined patient encounter is appended to the patient's medical record.

19. A computer-based system for interactively managing patient healthcare and evaluating patient kidney function, the system comprising:

a means for defining a patient's medical record;

a means for establishing the patient's estimated glomerular filtration rate based on the patient's medical record;

a means for generating at least one patient treatment recommendation based on the patient's medical record and estimated glomerular filtration rate; and

a means for calculating at least one treatment goal for the patient.

**IX. EVIDENCE APPENDIX**

None.

**X. RELATED PROCEEDINGS APPENDIX**

**None.**